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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,307	04/06/2001	David Mack	A-69192-1/DJB/JJD/AMS	7761

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/828,307

Applicant(s)

MACK ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 12-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Homology Search.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, claims 47-51 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that undue burden for co-examination of all of the enumerated Groups (Groups I-XIV) has not been established. Applicants' argue that to show undue burden resulting from searching difficulties, the Examiner must show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search (pp. 2).

The arguments have been carefully considered but they are not found persuasive for the following reasons.

According to the Restriction requirement that was mailed out on September 24, 2002, the Office Action enumerated fourteen groups of the following class and subclass:

Group I: Class 436, subclass 500

Group II: Class 530, subclass 387.1

Group III: Class 424, subclass 130.1

Group IV: Class 435, subclass 6

Group V: Class 424, subclass 184.1

Group VI: Class 514, subclass 1

Group VII: Class 424, subclass 130.1

Group VIII: Class 424, 178.1

Group IX: Class 514, subclass 44

Group X: Class 536, subclass 23.1

Group XI: Class 436, subclass 501

Group XII: Class 530, subclass 300

Group XIII: Class 530, subclass 300

Group XIV: Class 536, subclass 23.1

Between Groups I-VI and VIII-XII, the classification to which the Groups are restricted to are separate. Therefore, in accordance with the Applicants' argument, the Groups are determined to be properly restricted. It should be noted that Applicants' elected Group IV is classified differently from all of the enumerated groups.

Groups III and VII are classified under the same class and subclass, but are determined to be restrictable because the methods are completely different processes involving searches that are not coextensive. For example, Group III is drawn to a method for screening for modulators of CZA8 while the method of Group VII is drawn to a method of treating breast cancer. Therefore, the search required by Group III extends to a modulator that "modulates" the activity of a protein CZA8. However, the search of Group VII requires that the inhibitor to the protein CZA8 "treat" breast cancer, mandating searches that extend into the state of prior art, enablement, etc in the area of cancer therapeutics, all of which are not required for the method of Group III. With regard to Groups X and XIV, the products are not useable together because they are structurally different. For example, the subject matter of Group X is a biochip comprising a group of nucleic acids while the subject matter of Group XIV is drawn to an isolated (single) nucleic acid. Finally, with regard to Groups XII and XIII, the searches required by the two groups are not coextensive because the method of XII does not require the polypeptide of XIII. Further, the claimed method of XII is drawn to prognosis of individual with breast cancer which

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would also require searches that extend to the area of drug therapy. Such search is not required for the polypeptide of XIII, amounting to a search burden when searched together.

The requirement is still deemed proper and is therefore made FINAL.

Applicants are advised that no formal request had been made to cancel claim 11.

However Applicants' intention to cancel this claim is noted on page 3 of the response.

Therefore, claim 11 has been canceled.

Claims 1-10 and 12-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 and the dependent claims 48-51 are indefinite for the recitation of the phrase, "wherein a difference in said protein expression indicates that the first individual *has* breast cancer," because it is confusing how one can derive at a definitive conclusion that an individual "has" cancer based on expression analysis when the specification discloses less than 100% correlation of the claimed marker of SEQ ID NO: 2 to cancers (Figure 3). Amending the claims

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to recite the phrase, "individual is susceptible to cancer" (or similar in concept) would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 47, 50, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Penn et al. (US 2002/0048763 A1, published April 25, 2002, priority February 4, 2000).

Claim 47 is drawn to a method of diagnosing breast cancer or colorectal cancer comprising comparing the expression of a CZA8 gene or fragment thereof in a first patient tissue and a second normal tissue, wherein the difference indicates that the patient is susceptible to cancer. Claims 50 and 51 are drawn to specific embodiments wherein the expression is carried out by detecting SEQ ID NO: 2 and SEQ ID NO: 4, respectively.

Penn et al. disclose a method of diagnosing breast cancer by determining a patient gene expression profile to one or more reference (or normal) expression profiles [1367-1368], wherein the probes used in the expression profiles comprise single exon probes. The single exon probe of SEQ ID NO: 30587 encodes a protein which has 72 contiguous amino acid residues which correspond to the presently claimed SEQ ID NO: 2 (a fragment thereof). The single exon probe of SEQ ID NO: 38497 also encodes a protein which has 72 contiguous amino acid residues which correspond to the presently claimed SEQ ID NO: 4 (a fragment thereof). Therefore, the

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method disclosed by Penn et al. anticipate the presently claimed method of diagnosing breast cancer by comparing the expression of the fragment of CZA8 gene, wherein said fragment is a fragment of SEQ ID NO: 2 or 4.

Therefore, Penn et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penn et al. (US 2002/0048763 A1, published April 25, 2002, priority February 4, 2000) in view of Keyomarsi et al. (U.S. Patent No. 5,543,291, issued August 6, 1996).

Claims 48 and 49 are drawn to a method of diagnosing breast cancer via expression comparison of CZA8 gene or a fragment thereof, wherein said expression comparison is accomplished through use of antibodies.

Penn et al. disclose a method of diagnosing breast cancer by determining a patient gene expression profile to one or more reference (or normal) expression profiles [1367-1368], wherein the probes used in the expression profiles comprise single exon probes. The single exon probe of SEQ ID NO: 30587 encodes a protein which has 72 contiguous amino acid residues which correspond to the presently claimed SEQ ID NO: 2 (a fragment thereof) (See attached Homology Search report). The single exon probe of SEQ ID NO: 38497 also encodes a protein which has 72 contiguous amino acid residues which correspond to the presently claimed SEQ ID NO: 4 (a fragment thereof)(See Homology Search report). Therefore, the method disclosed by Penn et al. anticipate the presently claimed method of diagnosing breast cancer by comparing the expression of the fragment of CZA8 gene, wherein said fragment is a fragment of SEQ ID NO: 2 or 4.

Penn et al. do not employ antibodies which are specific for CZA8 for the expression assay, but rather employs a microarray of probes.

Keyomarsi et al. disclose a method of diagnosing the presence of human carcinoma, particularly human breast carcinoma, by assaying for presence of abnormal expression of various cyclins and CDKs in human breast cancer cell lines wherein the assay is achieved by use of cyclin E antibody specific for cyclin E protein (column 2, lines 5-17) as well as the well known method for generating monoclonal antibodies (column 4, lines 47-65) against a particular agent (in this case cyclin E).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Penn et al. with the teachings of Keyomarsi et al. because by doing so, one of ordinary skill in the art would have been able to isolate the expression pattern of CZA8 or fragment thereof for the purpose of diagnosing breast cancer via use of monoclonal antibody. Such combination of teachings would have been achieved with a reasonable expectation of success given the well established status of the art in the field of monoclonal antibody detection.

Therefore, the invention as claimed is obvious over the cited references.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 50 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of copending Application No. 09/608,821. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 50 of the instant application is dependent on independent claim 47 which is drawn to a method of diagnosing breast cancer without the use of SEQ ID NO: 2. The use of SEQ ID NO: 2 is required in the immediately dependent claim 50 of the instant application.

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Claim 7 of the '821 Application is drawn to a method of diagnosing breast cancer via use of SEQ ID NO: 2.

Therefore, the scope of the claims are determined to be identical, rendering the claims rejected under provision double patenting rejection.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yin et al. (U.S. Patent No. 6,455,678, issued September 24, 2002, priority April 23, 1997) disclose AC133, a nucleic acid and the encoded protein (SEQ ID NO: 2) sequence that exhibit 100% overall similarity match to that of the elected SEQ ID NO: 2 (see attached sequence homology search results). Yin et al., on column 18, lines 15-19, disclose that retinoblastoma cell lines, WERI-Rb-1 and the teratocarcinoma cell lines (cancerous sample), expressed detectable levels of AC133.

Yin et al., however, do not disclose or reasonably suggest that their protein is useful in diagnosing or detecting breast or colorectal cancer, but rather, on Table 1 (column 18), disclose that AC133 was not detectable in breast tumor and colon adenocarcinoma cell lines.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If


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applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

1/9/03




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

1/13/03